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June 11, 1999

Susan M. Pilch, Ph.D.

Team Leader, Nutrition Health Claims
and Dietary Supplements
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
-Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Dr. Pilch,

This letter confirms the content of the conversation you had with Eleanor (Miki) Kolton, JD, MSN, earlier today. In that conversation you explained that we should supplement the health claim petitions submitted for the three B vitamins and saw palmetto to include an explanation of the scientific methodology used to ascertain levels of the relevant ingredients contained in each finished product. You indicated that Association of Official Analytical Chemists (AOAC) methodologies are preferred, but not mandatory. You also stated that assay tests do not need to be conducted for the petitions. You agreed that it would be acceptable for us to submit the supplemental information within thirty days and that the petition process would not be impaired by that delay. We thank you for your assistance and intend to file the supplemental information promptly and in no event later than thirty days hence.

We look forward to future communication with you on this matter.

Sincerely,

Jonathan W. Emor Eleanor A. Kolton